REMARKS

Claims 52 and 53 are pending in the subject application. By this Amendment, applicants have amended claim 52 in a manner that is fully supported in the specification as filed at, *inter alia*, page 19, lines 27-30; and page 35, lines 4-9. Thus, these amendments do not raise any issue of new matter. Accordingly, upon entry of this Amendment, claims 52 and 53 will still be pending.

Election/Restriction

The Examiner acknowledged applicants' election with traverse of Group 14 (claims 52 and 53, with respect to SEQ ID NO: 14) in the response filed December 18, 2003. However, the Examiner concluded that applicants' traversal is not found persuasive because applicant has not sufficiently established that the restricted inventions are commensurate in scope, or that a search of each of the multiple sequences claimed would not be burdensome. The Examiner stated that the restriction requirement is still deemed proper and is therefore made FINAL.

Rejection Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 52 and 53 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner stated that applicants claim an isolated polypeptide, encoded by at least a portion of SEQ ID NO:14 (i.e., a fragment of a polypeptide encoded by SEQ ID NO:14), that

uniquely defines a herpesvirus associated with Kaposi's sarcoma (KS). According to the Examiner, the claims read on a broad genus of peptide fragments which may or may not define a herpesvirus associated with KS.

The Examiner stated that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. The Examiner further stated that in the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

The Examiner stated that applicants claim a fragment of a polypeptide that uniquely defines a herpesvirus associated with KS by function only, without any disclosed or known correlation between the elements and their function. The Examiner also stated that the specification provides teachings regarding the full-length protein that is encoded by SEQ ID NO:14, but that the specification does not teach which regions of the polypeptide are unique to a herpesvirus associated with KS. The Examiner further stated that applicants presume that any fragment of the polypeptide encoded by SEQ ID NO:14 can serve as an identifying polypeptide for such a herpesvirus, simply because SEQ ID NO:14 is uniquely associated with such a herpesvirus.

The Examiner stated that SEQ ID NO:14, however, encodes a polypeptide that is 581 (*sic* 580) amino acids in length, and that

the claims read on any di-amino acid sequence (or higher) within this 581-amino acid sequence, each of which must identify only a herpesvirus specifically associated with KS. The Examiner also stated that the specification does not provide any guidance as to which sequences would be necessarily and selectively associated with KS. According to the Examiner, while it is clear that SEQ ID NO:14 encodes a protein that appears to uniquely define a herpesvirus associated with KS, the skilled artisan cannot envision a sufficient number of polypeptide fragments within the full length protein (that uniquely define the herpesvirus) from the instant specification because the specification does not describe these polypeptides. The Examiner concluded that, consequently, the instant specification does not meet the written description requirement for the claimed genus of polypeptides.

In addition, the Examiner stated that the prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. The Examiner also stated that there is no description in the prior art that allows one to envision a representative number of polypeptide fragments encoded by a portion of SEQ ID NO:14, wherein the encoded polypeptides necessarily and selectively define a herpesvirus associated with KS. The Examiner stated that because there is no such disclosure of the relevant structural or functional features of polypeptide fragments encoded by a portion of SEQ ID NO:14, one of skill in the art could not envision the claimed invention.

The Examiner concluded that the skilled artisan would not be able to envision the claimed invention by relying on the teachings of the prior art or the instant specification, and that applicants have therefore not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

In response, applicants respectfully traverse the Examiner's rejection.

Applicants note that claim 52, as amended, makes clear that the claimed isolated peptide is encoded by a nucleotide sequence which is at least 30 nucleotides in length and is within SEQ ID NO. 14, which peptide uniquely defines a herpesvirus associated with KS.

Applicants note that, with respect to individual nucleotide sequences of at least 30 nucleotides that are found within SEQ ID NO:14, it would be routine to identify a large number of such ≥ 30-nt sequences from the nucleotide sequence of SEQ ID NO:14, based on the specification. Moreover, using tools available in the prior art, one skilled in the art could easily determine which peptides encoded by such ≥ 30-nt-long sequences uniquely define a herpesvirus associated with Kaposi's sarcoma. For example, a skilled practioner could perform a BLAST (Basic Local Alignment Search Tool) search of publicly accessible peptide databases using the polypeptide encoded by SEQ ID NO:14, i.e., using SEQ ID NO:15 as a query sequence (see http://www.ncbi.nlm.nih.gov/BLAST/). This type of BLAST search, which typically can be completed in a few minutes, would identify peptide sequences that share homology with SEQ ID NO:15. The BLAST program would also align peptide homologs with the SEQ ID NO:15 sequence. Thus, any peptide encoded by a ≥ 30-nt sequence of SEQ ID NO:14 which does not uniquely define a KS-associated herpesvirus could be easily identified. Accordingly, applicants maintain that provision of the complete nucleotide sequence of SEQ ID NO:14 is sufficient disclosure of a relevant identifying characteristic, i.e., structure, to show that applicants were in possession of the claimed genus.

Applicants maintain that the Examiner's statement that "the prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification" is without merit. As discussed above, a widely used bioinformatics tool such as the BLAST program, which was available in the prior art, clearly provides sufficient information to overcome any perceived deficiencies of the subject specification.

Furthermore, contrary to the Examiner's assertion, applicants do not presume that any fragment of the polypeptide encoded by SEQ ID NO:14 can serve as an identifying polypeptide for such a herpesvirus associated with KS simply because SEQ ID NO:14 is uniquely associated with such a herpesvirus. Applicants do, however, contend that the information provided in the specification is sufficient for the easy identification of peptides encoded by ≥ 30-nt sequences within SEQ ID NO:14, which peptides uniquely identify a KS-associated herpesvirus.

Thus, applicants maintain that independent claim 52, as amended, and claim 53 which depends from it, satisfy the written description requirement of 35 U.S.C. §112, first paragraph.

The Examiner also rejected claims 52 and 53 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for the full length SEQ ID NO:14, allegedly does not reasonably provide enablement for the portions of the polypeptide (i.e., fragments) that uniquely define a herpesvirus associated with KS. The Examiner further stated that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Examiner stated that the test of enablement is whether one skilled in the art could make and use the claimed invention from

the disclosures in the specification coupled with information known in the art without undue experimentation (*citing United States v. Telectronics.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). The Examiner also stated that whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors, outlined in *Ex parte Forman,* 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands,* 8 USPQ2d 1400 (Fed. Cir. 1988). The Examiner listed the most relevant factors and discussed their relevance to the instant application. Applicants reproduce and comment on the Examiner's statements as set forth below.

Nature of the invention

The Examiner stated that the nature of the invention is any polypeptide fragment encoded by a portion of SEQ ID NO:14, wherein said polypeptide fragment necessarily and selectively defines a herpesvirus that is associated with KS. The Examiner also stated that, in particular, such polypeptides can be used to generate antibodies, which can then be used as diagnostic tools for identifying the herpesvirus in (potentially) infected patients.

Applicants note that the nature of the invention to which claim 52, as amended, is directed is an isolated peptide encoded by a nucleotide sequence which is at least 30 nucleotides in length and is within SEQ ID NO. 14, which peptide uniquely defines a herpesvirus associated with KS.

Scope of the invention

The Examiner asserted that the scope of the invention is very broad, encompassing any sized fragment found within the 581-amino acid protein encoded by SEQ ID NO:14. The Examiner noted that this includes di-peptides and tri-peptides. The Examiner stated that it is, however, unclear which of these peptides

necessarily and selectively defines a herpesvirus that is associated with KS.

In response, applicants note that the peptide claimed in claim 52, as amended, must be encoded by a nucleotide sequence which is at least 30 nucleotides in length and is within SEQ ID NO. 14, i.e., the peptide must be ≥ about 10 amino acid residues long and would not include di- and tri-peptides. As discussed hereinabove, relevant peptide sequences that define a herpesvirus associated with KS can be easily identified by, for example, doing a BLAST search using SEQ ID NO:15 as a query sequence.

State of the art and level of skill in the art

The Examiner stated that the state of the art is silent with regard to which peptide fragments encoded by portions of SEQ ID NO:14 *necessarily and selectively* define a herpesvirus that is associated with KS. The Examiner also stated that, however, the state of the art clearly identifies proteins that are not encoded by SEQ ID NO:14, many of which may (or may not) contain peptides that *are* encoded by *portions* of SEQ ID NO:14. The Examiner further stated that these polypeptides could not uniquely define a herpesvirus associated with KS, since they also can be used to define another protein. The Examiner stated that because it is unclear which portions of SEQ ID NO:14 encode peptides that are also encoded in other proteins, it is unpredictable which of these peptides encoded by portions of SEQ ID NO:14 uniquely define a herpesvirus associated with KS.

In response, applicants note that just as techniques in the art can be used to identify peptides encoded by fragments of SEQ ID NO:14 which do not uniquely define a herpesvirus associated with KS, the same techniques can also be used to identify peptides of ≥ 10 amino acids encoded by fragments of SEQ ID NO:14 which *do* define a KS-associated herpesvirus.

The Examiner also stated that there are a number of proteins from organisms/viruses that have not been sequenced/identified. According to the Examiner, because these proteins are unknown, the skilled artisan could not predict if a particular peptide encoded by a portion of SEQ ID NO:14 actually did *uniquely define* a herpesvirus associated with KS, because that polypeptide might be present in another protein that is not associated with a herpesvirus or KS. The Examiner stated that, as a result, the skilled artisan would turn to the instant specification for guidance on making and using the claimed invention.

Applicants respectfully disagree with the Examiner's stated position. Applicants contend that the mere possibility of the existence of an unidentified nucleic acid sequence cannot be used to deny the demonstrated uniqueness of any given sequence. Applicants note that a logical extension of the Examiner's reasoning would suggest that the polypeptide encoded by the full-length SEQ ID NO:14 sequence does not uniquely identify a KS-associated herpesvirus since the identical polypeptide could conceivably be produced by an unknown virus or organism. Applicants maintain that such a view is untenable. Indeed, the Examiner himself stated more than once in the Office Action that that SEQ ID NO:14 clearly encodes a protein that appears to uniquely define a herpesvirus associated with KS.

Number of working examples and guidance provided by applicant

The Examiner stated that the instant specification only defines the full-length protein that is encoded by SEQ ID NO:14, which appears to uniquely define the herpesvirus characterized in the instant specification. The Examiner also stated that, however, there is no dissection of the protein, whereby the fragments of the protein (i.e., those portions encoded by a portion of SEQ ID NO:14) that also *uniquely* define the herpesvirus are clearly taught. The Examiner further stated that without a teaching of

which peptide fragments encoded by portions of SEQ ID NO:14 are unique to a herpesvirus associated with KS, the skilled artisan could not make or use the claimed invention.

Applicants have addressed these points hereinabove. Briefly, applicants maintain that a vast array of ≥ 30-nt-long sequences can be readily identified from the disclosure of the SEQ ID NO:14 sequence in the subject application. Out of the peptides encoded by this vast array, peptide sequences that uniquely define a herpesvirus associated with KS can be easily identified by comparison with peptide databases, for example, by performing a BLAST search.

Unpredictability of the art and amount of experimentation required

The Examiner also stated that the instant claims require a great deal of empirical, undue and unpredictable trial and error experimentation for their full scope to be enabled. The Examiner also stated that the skilled artisan would need to empirically determine each polypeptide encoded by SEQ ID NO:14, and then determine which of these polypeptides are not present in *any* of the other known proteins. The Examiner further stated that even if the polypeptide is found only once, it cannot be considered to uniquely define a herpesvirus associated with KS.

The Examiner stated that, furthermore, the polypeptide must still be unique in the face of other unknown proteins. The Examiner also stated that in the instance where a polypeptide as encoded by a portion of SEQ ID NO:14 also encodes an unknown protein (or portion thereof) (*sic*), the polypeptide no longer meets the functional limitation of being unique to a herpesvirus associated with KS. The Examiner further stated that because the skilled artisan cannot predict any of these instances without an undue

amount of trial and error experimentation, the full scope of the claims is not enabled.

The Examiner stated that whereas it certainly appears that the full-length protein encoded by SEQ ID NO:14 uniquely defines a herpesvirus associated with KS, there are, however, no teachings in either the prior art or in the instant specification which defines the regions of the polypeptide that are not present in any other protein, both known and unknown. The Examiner also stated that, as a result, the skilled artisan would have to perform trial and error experimentation of an undue nature, to effectively define the broad scope of the claimed invention. The Examiner concluded that, as a result, the broad scope of the claimed invention cannot be considered enabled because it cannot be made (and therefore cannot be used) without a burdensome amount of trial and error experimentation.

In response, applicants respectfully traverse. As discussed above, identifying peptides, encoded ≥ 30-nt-long nucleic acid sequences within SEQ ID NO:14, which uniquely define a herpesvirus associated with KS can be easily achieved by a person skilled in the art simply by, for example, performing a BLAST search. Applicants emphasize that this procedure is routinely done in the art and does not require any undue experimentation.

Thus, applicants maintain that claim 52, as amended, and dependent claim 53 satisfy the enablement requirement of 35 U.S.C. §112, first paragraph.

Conclusion

In view of the remarks made herein, applicants respectfully request that the Examiner reconsider and withdraw the rejections

set forth in the Office Action and earnestly solicit allowance of both claims pending in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents, P.O. Box 1450
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